ATTRACTION Trial

Iliofemoral DVT

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ATTRACTION Trial: Iliofemoral DVT

Disclosures

ATTRACTION Trial – Steering Committee

Pharmacomechanical Catheter-Directed Thrombolysis for Deep-Vein Thrombosis


New Engl J Med 2017;377:2240 - 52

The ATTRACTION Trial

Study Organization

- NIH sponsored
- Phase III study
- Randomized, controlled
- Multicenter, open-label
- Assessor-blinded
- 692 Patients randomized…. Anticoagulation alone vs. Anticoagulation + PCDT

The ATTRACTION Trial

Symptomatic Proximal DVT

Efficacy Outcomes

- Post-Thrombotic Syndrome @ 24 months: Villalta Score > 4
- Venous ulcer
- Unplanned endovenous procedure to treat symptoms beyond six months post randomization

Vedanthan S., et al
NEJM 2017;377:2240
**Efficacy Outcomes**

- **Secondary**
  - Severity of PTS (Villalta ≥ VCSS)
  - **Moderate - Severe PTS** (Villalta ≥ 10)
  - Major Non PTS Rx Failure
    - Endovas. procedure for severe symptoms
    - Venous gangrene
    - Amputation

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**The ATTRACT Trial**

**Efficacy Outcomes**

- **Primary Outcomes**
  - **Outcome**
    - PCDT (N=336)
    - Control (N=355)
    - **p-value**
  - **PTS TOTAL**
    - 47% 48% 0.56
  - **Major Bleed:** (10 days)
    - 1.7% 0.3% 0.049

*This is the outcome that drove opinion about the ATTRACT Trial results!*

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**Focused Results…**

Catheter-based strategies of thrombus removal are focused on patients with iliofemoral DVT……

……Therefore, results from IFDVT patients will be the most meaningful in guiding patient care!

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**The ATTRACT Trial**

**Patients**

- **391 Iliofemoral DVT**
- Randomized: PCDT vs. Anticoagulation
- **Primary Endpoints:** Any PTS (Villalta score >4)
- Major bleeding
  - **Secondary Endpoints:**
    - Moderate or Severe PTS
    - Pain at 30 days
    - Swelling at 30 days
    - QOL at 2 years

**Post-Thrombotic Syndrome**

- **Results**
  - **Villalta >4**
    - PCDT (N=196) 49%
    - Control (N=195) 51%
    - **P-Value** 0.59
  - **VCSS**
    - 30% 40% 0.034

*Result appears no different than overall trial result. But are they?*
**The ATTRACT Trial: Iliofemoral DVT**

**Moderate-Severe PTS**

<table>
<thead>
<tr>
<th></th>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Villalta &gt;9</td>
<td>18%</td>
<td>28%</td>
<td>0.021</td>
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</tbody>
</table>

Control patients had 56% increased risk of moderate – severe PTS vs. PCDT!

**Severe PTS**

<table>
<thead>
<tr>
<th></th>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Villalta &gt;14</td>
<td>8.7%</td>
<td>15%</td>
<td>0.048</td>
</tr>
<tr>
<td>VCSS</td>
<td>6.6%</td>
<td>14%</td>
<td>0.013</td>
</tr>
</tbody>
</table>

Control patients had a 72% increased risk of severe PTS vs. PCDT!

**Villalta Score: Post Rx**

<table>
<thead>
<tr>
<th></th>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.82</td>
<td>5.43</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Pain**

- 7 Point Scale-

<table>
<thead>
<tr>
<th></th>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 10</td>
<td>-1.76</td>
<td>-1.25</td>
<td>0.0093</td>
</tr>
<tr>
<td>Day 30</td>
<td>-2.36</td>
<td>-1.80</td>
<td>0.0082</td>
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</table>

**Leg Circumference**

<table>
<thead>
<tr>
<th></th>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 10</td>
<td>-0.79</td>
<td>0.22</td>
<td>0.0019</td>
</tr>
<tr>
<td>Day 30</td>
<td>-1.37</td>
<td>-0.10</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**QOL: Veines**

- 24 Months -

<table>
<thead>
<tr>
<th></th>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td>Overall</td>
<td>28.6</td>
<td>23.0</td>
<td>0.029</td>
</tr>
<tr>
<td>Symptoms</td>
<td>21.5</td>
<td>16.2</td>
<td>0.043</td>
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</table>
**The ATTRACT Trial: Iliofemoral DVT**

**Bleeding**

-10 Days-

<table>
<thead>
<tr>
<th>Bleed</th>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td>Major</td>
<td>1.5%</td>
<td>0.5%</td>
<td>0.32</td>
</tr>
<tr>
<td>Any</td>
<td>3.6%</td>
<td>2.1%</td>
<td>0.36</td>
</tr>
</tbody>
</table>

*No Intracranial Bleed*

**Recurrent VTE**

-24 Months-

<table>
<thead>
<tr>
<th>Time</th>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Days</td>
<td>5.8%</td>
<td>3.1%</td>
<td>0.22</td>
</tr>
<tr>
<td>24 Months</td>
<td>13.0%</td>
<td>9.2%</td>
<td>0.21</td>
</tr>
</tbody>
</table>

**Deaths at 24 months**

<table>
<thead>
<tr>
<th>PCDT (N=196)</th>
<th>Control (N=195)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1%</td>
<td>3.1%</td>
<td>0.99</td>
</tr>
</tbody>
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**Conclusions**

- The Primary Endpoint...Reduction of Any PTS was not met with PCDT!
  (Recall that 14% had normal Villalta and 47% had normal/mild Villalta Scores at baseline)
- Therefore, is any PTS the meaningful endpoint for patients and clinicians, considering the sensitivity of the Villalta Score?

**How should the ATTRACT Trial results change our practice?**

For those offering PCDT to patients with moderate/severe symptoms of IFDVT, the ATTRACT Trial confirms that approach!

Those who do not offer IFDVT patients, with moderate/severe symptoms, a catheter based strategy of thrombus removal, they should study the focused results of ATTRACT, and seriously consider catheter based Rx!
Inova
Heart and Vascular Institute

Thank You!